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103D CONGRESS
1ST SESSION

H. R. 2147

To amend the Federal Food, Drug, and Cosmetic Act to regulate the manufacture, labeling, sale, distribution, and advertising and promotion of tobacco and other products containing nicotine, tar, additives and other potentially harmful constituents, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 1993

Mr. SYNAR (for himself, Mr. DURBIN, Mr. ANDREWS of Texas, Mr. WYDEN, Mrs. COLLINS of Illinois, Ms. SCHENK, Mr. BLACKWELL, Mr. WHEAT, Mr. HUFFINGTON, and Mr. EVANS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to regulate the manufacture, labeling, sale, distribution, and advertising and promotion of tobacco and other products containing nicotine, tar, additives and other potentially harmful constituents, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Fairness in Tobacco and Nicotine Regulation Act of 1993''.

(b) REFERENCE.—Whenever in this Act (other than sections 5(b)(1) and 5(b)(2)) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. FINDINGS.

The Congress finds that—

(1) Cigarette smoking and tobacco use account for approximately 450,000 deaths each year in the United States.

(2) Cigarette smoking accounts for approximately $65 billion in lost productivity and health care costs.

(3) Environmental tobacco smoke is a cause of disease in nonsmokers.

(4) In spite of well established dangers of cigarette smoking and tobacco use, no Federal regulatory agency has the authority to regulate the manufacture, sale, distribution, labeling, and advertising of such products.

(5) Tobacco is as addictive as cocaine and heroin.

(6) The tobacco industry spends approximately $4 billion each year to promote its products.

(7) The tobacco industry's voluntary advertising code which was enacted to prohibit the use of images of sexual attraction, sophistication, and athletic abilities and the making of implied health claims has for the last 30 years not been followed or enforced.

(8) Each day 3,000 children try cigarettes for the first time and many become life-long addicted smokers.

(9) There is no Federal minimum age of sale of cigarettes and tobacco products.

(10) The labeling of tobacco products is inadequate as to provide smokers and nonsmokers alike with full and complete information about tobacco products.

(11) The tobacco industry adds chemical additives to their products that are neither disclosed to the public or tested for health and safety in a comparable manner to food.

(12) There is no listing of chemical constituents found in mainstream and sidestream smoke (including benzene, arsenic, cyanide, etc.).

(13) The Food and Drug Administration is the most qualified Federal agency to comprehensively regulate tobacco products.

(14) It is inconsistent for the Food and Drug Administration to regulate the manufacture, sale, distribution, labeling, advertising, and promotion of other nicotine containing products used as substitutes for cigarette smoking and tobacco use and not be able to regulate tobacco products in a comparable manner.

SEC. 3. DEFINITIONS.

Section 201 (21 U.S.C. 321) is amended by adding at the end thereof the following new paragraphs:

''(gg) The term 'tobacco product' means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, snuff, and chewing tobacco.

''(hh) The term 'tobacco additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any tobacco product.

''(ii) The term 'constituent' means any element of cigarette mainstream or sidestream smoke which is present in quantities which represent a potential health hazard or where the health effect is unknown.

''(jj) The term 'tar' means mainstream total articulate matter minus nicotine and water.

SEC. 4. ENFORCEMENT.

Section 301 (21 U.S.C. 331) is amended by adding at the end thereof the following new subsection:

''(u) The manufacture, labeling, sale, distribution, advertising, and promotion of tobacco products in violation of regulations of the Secretary pursuant to section 701.''

SEC. 5. REGULATION OF TOBACCO PRODUCTS.

(a) REGULATION.—The Federal Food, Drug, and Cosmetic Act is amended by redesignating chapters VII, VIII, and IX as chapters VIII, IX, and X, respectively, and by adding after chapter VI the following:

''CHAPTER VII—TOBACCO PRODUCTS

''REGULATIONS

''SEC. 701. (a) PROMULGATION.—The Secretary shall promulgate regulations governing the manufacture, distribution, sale, labeling, and advertising and promotion of tobacco products which are consistent with the manner in which other products which are ingested into the body are regulated, except that the Secretary may not promulgate a regulation which prohibits the sale and distribution of a tobacco product solely on the basis of the fact that tobacco causes disease. Such regulations shall be promulgated not later than 12 months after the date the Secretary receives the recommendations of the Tobacco and Nicotine Products Advisory Committee under section 702(e).

''(b) MINIMUM REQUIREMENTS.—

''(1) SALE OR DISTRIBUTION.—Regulations under subsection (a) shall with respect to the sale or distribution of tobacco products make unlawful—

''(A) the sale of a tobacco product intended for use by man to any person under the age of 18 years or under such other age greater than 18 years as the State in which the sale occurs may establish by law,

''(B) the distribution of a tobacco product as a free sample or the distribution of a tobacco product as a result of coupons or other materials which allow for the obtaining of free or discounted tobacco products, or

''(C) the sale or distribution of a tobacco product if the label fails to carry the following statement: ''Federal Law Prohibits Sale To Minors''.

The Secretary shall enforce this paragraph in a manner that can reasonably be expected to ensure that tobacco products are not made available to individuals under the age of 18 years.

''(2) LABELING.—

''(A) IN GENERAL.—Regulations under subsection (a) with respect to the labeling of to-

bacco products shall require that a tobacco product shall be deemed misbranded if—

''(i) it is not in compliance with the labeling requirements of the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act of 1986,

''(ii) it does not include a warning and information about the dangers associated with environmental tobacco smoke,

''(iii) it does not provide a list of chemical additives and constituents found in tobacco products and tobacco smoke, or

''(iv) it contains any implied or direct health claim, including the use of such terms as light, lower tar, medium, lowest, or nicotine free, unless such terms have been approved by the Secretary on the basis of sound scientific data and the Secretary determines that such terms will have a significant impact on the health consequences associated with cigarette smoking and other tobacco use.

''(B) SPECIFIC INFORMATION.—The Secretary may include in regulations under sub-

section (a) relating to labeling of tobacco products labeling requirements requiring manufacturers of tobacco products to provide to consumers by way of labeling of packages, package inserts, or other means—

''(i) information about the adverse effects of tobacco products,

''(ii) adequate warnings and directions for use,

''(iii) contraindications,

''(iv) adequate warnings against use in pathological conditions, and

''(v) any other information deemed necessary by the Secretary.''.

''(3) ADVERTISING AND PROMOTION.—

''(A) CONSISTENCY.—Regulations under subsection (a) with respect to the advertising and promotion of tobacco products shall be consistent with regulations governing the advertising and promotion of prescription drugs, especially such drugs which contain nicotine.

''(B) SPONSORSHIP.—In such regulations, the Secretary shall make it unlawful for any sporting event, cultural event, or any other event or function open to the public to be spon-

sored by a tobacco manufacturer who at such event or function displays the name or logo of any brand of cigarettes or tobacco product of such manufacturer.

''(C) CONSTRUCTION.—Such regulations and the authority provided the Secretary does not repeal or modify the authority of the Federal Trade Commission in carrying out its responsibilities.

''(4) MANUFACTURING.—Regulations under subsection (a) governing the manufacture of tobacco products shall—

''(A) require that all additives used in the manufacture of tobacco products are safe,

''(B) classify as a drug any nicotine containing product which does not meet the definition of a tobacco product, and

''(C) have the authority to subpoena any document which relates to the manner in which tobacco products are manufactured.

''ADVISORY COMMITTEE

''SEC. 702. (a) ESTABLISHMENT.—To assist in the development of regulations required by section 701, there is established in the Food and Drug Administration a Tobacco and Nicotine Products Advisory Committee (herein-

after in this section referred to as the ''advisory committee'').

''(b) MEMBERSHIP.—

''(1) SECRETARIAL APPOINTMENTS.—The Secretary shall appoint to the advisory committee 10 individuals who are qualified by training and experience to evaluate and make recommendations for the issuance of regulations governing the manufacture, distribution, sale, labeling, and advertising and promotion of tobacco products which, to the greatest extent practical, promote and protect the public's health without banning the product. The 10 members shall consist of—

''(A) one expert in the field of nicotine addiction,

''(B) one expert in the field of pharmacology,

''(C) one expert in the field of food and drug law,

''(D) one expert in the field of marketing and promotion of products,

''(E) one expert in the field of public education,

''(F) one expert in the field of toxicology,

''(G) two representing the interests of family medicine, internal medicine, or pediatrics, and

''(H) two consumer representatives from the public health community.

''(2) EX OFFICIO.—The Directors of the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Drug Abuse, the Centers for Disease Control and Prevention, and the Surgeon General of the United States shall serve as ex officio members of the advisory committee.

''(3) CHAIRMAN.—The chairman of the advisory committee shall be appointed by the Secretary with the advice and consent of the Commissioner of Food and Drugs.

''(4) APPOINTMENT DATE.—The Secretary shall make appointments to the advisory committee within 60 days of the date of the enactment of this section.

''(c) FUNCTION.—The advisory committee shall give specific consideration to—

''(1) reviewing the available scientific evidence on the effects of tobacco products on human health, including the effects of environmental tobacco smoke on nonsmokers,

''(2) reviewing the manufacturing process of tobacco products, including the use of additives, sprayed on chemicals, product development, and product manipulation,

''(3) reviewing the role of nicotine as part of the smoking habit, including its addictive properties and health effects,

''(4) reviewing the marketing and promotional techniques used by tobacco manufacturers in selling their products, and

''(5) reviewing current Federal, State, and local laws governing the manufacture, distribution, sale, labeling, and advertising and promotion of tobacco products.

''(d) AUTHORITY.—The advisory committee may for the purpose of carrying out its functions hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the advisory committee deems appropriate.

''(e) RECOMMENDATIONS.—The advisory committee shall make recommendations respecting the issuance of regulations under section 701 within 12 months of the appointment of the 10 members of the advisory committee.

''REGISTRATION

''SEC. 703. Each tobacco product manufacturer shall register with the Secretary. Any such manufacturer who

is in business on the date of the enactment of this Act shall register with the Secretary not later than 120 days after the date of the enactment of this section.

''TOBACCO PRODUCT MANUFACTURER FEE

''SEC. 704.(a) FEE PURPOSE.—For the purpose of paying the costs of implementing this chapter, each tobacco product manufacturer shall pay an annual fee established pursuant to paragraph (2). Such fee shall be payable on or before January 31 of each year.

''(b) ESTABLISHMENT BY THE SECRETARY.—Subject to the amount established in appropriation Acts, the annual tobacco product manufacturer fee shall be determined by the Secretary based upon the total market share for each brand of tobacco product.

''(c) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by subsection (a)—

''(A) shall be collected in each fiscal year in an amount equal to the amount specified in appropriation Acts for such fiscal year, and

''(B) shall only be collected and available to defray the costs of implementing this chapter.''.

(b) CONFORMING AMENDMENTS.—

(1) TOBACCO LABELING AND ADVERTISING.—The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.) is amended—

(A) in section 4 (15 U.S.C. 1333) by striking out ''SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide'' each place it appears and inserting in lieu thereof ''SURGEON GENERAL'S WARNING: Smoking is Addictive. Once You Start You May Not Be Able to Stop'', and

(B) by repealing sections 5(b) and 7 (15 U.S.C. 1334(b), 1335a).

(2) SMOKELESS TOBACCO.—The Comprehensive Smokeless Tobacco Health Education Act of 1986 is amended—

(A) in section 3(a)(1) (15 U.S.C. 4402(a)(1)), by striking out the close quotation marks and the period following at the end and inserting the following:

''WARNING: THIS PRODUCT IS ADDICTIVE. ONCE YOU START YOU MAY NOT BE ABLE TO QUIT'.'',

(B) in section 3(b)(1) (15 U.S.C. 4402(b)(1), by inserting in the matter in subparagraph (B) the following:

(3) RECORDS OF INTERSTATE SHIPMENT.—Section 703 (21 U.S.C. 373) is amended—

(A) by striking out ''or cosmetics'' and inserting in lieu thereof ''cosmetics, or tobacco products'', and

(B) by striking out ''or cosmetic'' and inserting in lieu thereof ''cosmetic, or tobacco product''.

(4) FACTORY INSPECTION.—Section 704 (21 U.S.C. 374) is amended—

(A) in subsection (a)(1), by striking out ''or cosmetics'' and inserting in lieu thereof ''cosmetics, or tobacco products'',

(B) in subsection (a)(1), by striking out ''or restricted devices'' each place it appears and inserting in lieu thereof '', restricted devices, or tobacco products'', and

(C) in subsection (b), by striking out ''or cosmetic'' and inserting in lieu thereof ''cosmetic, or tobacco product''.

(5) REDESIGNATIONS.—Sections 701 through 711 are redesignated as sections 801 through 811, respectively, section 721 is redesignated as section 821, sections 731 through 736 are redesignated as sections 831 through 836, respectively, sections 801 through 803 are redesignated as sections 901 through 903, respectively, sections 901 through 903 are redesignated as sections 1001 through 1003, respectively, and the references to the redesignated sections are changed to refer to the sections as redesignated.

(c) SECRETARIAL AUTHORITY.—The Secretary of Health and Human Services may, by regulation—

(1) modify the warning labels required by the Federal Cigarette Labeling and Advertising Act and

the Comprehensive Smokeless Tobacco Health Education Act of 1986 if the modification in the content of the label does not weaken the health message contained in the label and is in the best interests of the public health, and

(2) increase the size and placement of such required labels.

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